UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

OLUWAKEMI ADEWOL, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:22 CV 254 CDP
	)	
FRICKENSCHMIDT FOODS LLC, et al.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

In this putative class action, named plaintiffs Oluwakemi Adewol, Keisha Jackson, and Jemilat Suleiman allege that defendants Frickenschmidt Foods LLC and Wicked Cutz LLC violated various state laws by mislabeling their Teriyaki Beef Wicked Cutz Beef Stick as gluten free. Pending before the Court is Frickenschmidt's motion to dismiss. In a previous order, I ruled on several of the parties' motions but delayed ruling on the motion to dismiss until Plaintiffs had the opportunity to respond to a preemption argument raised for the first time in Frickenschmidt's reply brief. Plaintiffs have now done so, and the motion is ready for ruling. As explained in detail below, I will grant Frickenschmidt's motion because I agree Plaintiffs' claims are preempted by federal law.

Background

The relevant facts of this dispute are detailed in the court's previous order. In short, Defendants Frickenschmidt and Wicked Cutz produce, market, and distribute their "Teriyaki Beef Wicked Cutz Beef Sticks" (or just "the Product") throughout the United States. On February 22, 2022, the United States Department of Agriculture's Food Safety and Inspection Service ("FSIS") announced that Frickenschmidt voluntarily recalled approximately 5,795 pounds of the Product due to misbranding. It explained that "[t]he product contains and declares wheat as an ingredient but has an incorrect statement of 'gluten free' on the label." (ECF 41-1 at p. 2.) Plaintiffs Oluwakemi Adewol, Keisha Jackson, and Jemilat Suleiman allege that they paid a substantial premium for the Product because it was labeled as gluten free. They claim they would not have purchased it if they knew it contained gluten.

In their amended complaint, Plaintiffs assert claims on behalf of a Multi-State Consumer Class[1], Maryland Class, Missouri Class, and Nationwide Class. Each class is made up of purchasers of the Product in each respective jurisdiction. In Count 1, they claim on behalf of the Multi-State Consumer Class that Defendants violated the consumer protection statutes of several states by engaging

[1] The states comprising the Multi-State Consumer Class are California, Florida, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, Pennsylvania, Oregon, and Washington.

in "unfair or deceptive business practices in the conduct of trade or commerce." (ECF 5 at p. 19.) In the alternative to Count 1, Counts 2 and 3 allege on behalf of the Maryland and Missouri Classes that Defendants violated Maryland and Missouri's consumer protection statutes by labeling the Product "gluten free" when it in fact contained gluten. Finally, Counts 4 through 6 allege breach of express warranty, breach of implied warranty, and unjust enrichment on behalf of the Nationwide Class. Plaintiffs seek compensatory and punitive damages, as well as an injunction prohibiting Defendants from selling the misbranded product.

On June 6, 2022, Frickenschmidt filed a "Motion to Dismiss First Amended Class Action Complaint and Strike Allegations or, In the Alternative, Motion for a More Definite Statement." It argues, among other things, that Plaintiffs' claims are preempted by federal law. Defendant originally argued that Plaintiffs' claims were preempted by the Federal Food, Drug and Cosmetic Act and the Food and Drug Administration's extensive regulation of "gluten free" labeling. But after Plaintiffs responded that the FDCA and the FDA's regulations do not apply to Defendants' meat products, Frickenschmidt argued in its reply brief that Plaintiffs' claims are expressly preempted by the Federal Meat Inspection Act (FMIA).

Motion to Dismiss Standard

A claim may be dismissed if it fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In ruling on a motion to dismiss, the Court

"must accept as true all of the complaint's factual allegations and view them in the light most favorable to the Plaintiff[.]" *Stodghill v. Wellston School Dist.*, 512 F.3d 472, 476 (8th Cir. 2008). However, "the Court is not bound to accept as true a legal conclusion couched as a factual allegation." *Warmington v. Bd. of Regents of Univ. of Minn.*, 998 F.3d 789, 796 (8th Cir. 2021) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). To avoid dismissal, a complaint must include "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

In reviewing the amended complaint, the Court construes it liberally and draws all reasonable inferences from the facts in Plaintiffs' favor. *Monson v. Drug Enforcement Admin.*, 589 F.3d 952, 961 (8th Cir. 2009). The Court generally ignores materials outside the pleadings but may consider materials that are part of the public record or materials that are necessarily embraced by the pleadings. *Miller v. Toxicology Lab. Inc.*, 688 F.3d 928, 931 (8th Cir. 2012). Matters necessarily embraced by the pleadings include "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned." *Zean v. Fairview Health Servs.*, 858 F.3d 520, 526 (8th Cir. 2017) (quoting *Miller*, 688 F.3d at 931 n.3).

Discussion

Congress enacted the Federal Meat Inspection Act in part to ensure that meat products are properly marked and labeled. 21 U.S.C. § 602. To that end, it prohibits the sale of meat products with false or misleading labels, 21 U.S.C. § 607(d), and delegates regulation of meat products to the USDA. Until March 20, 2023, the USDA required submission of labeling applications for "negative claims (e.g., 'gluten free')" to the Food Safety Inspection Service (FSIS) before the label could be used on any meat product. 9 C.F.R. § 412.1(e) (2022); 88 Fed. Reg. 2798-01 (Jan. 18, 2023). This preapproval process includes an evaluation of whether the label is "false or misleading." *See Meaunrit v. ConAgra Foods Inc.*, No. C 09-02220 CRB, 2010 WL 2867393, at *6 (N.D. Cal. July 20, 2010) (citing 21 U.S.C. § 457).

The FMIA also contains a preemption clause, 21 U.S.C. § 678, that provides: "Marking, labeling, packaging, or ingredient requirements . . . in addition to, or different than, those made under this chapter may not be imposed by any State[.]" This preemption clause "sweeps widely[.]" *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459 (2012). It "prevents a [s]tate from imposing any additional or different—even if nonconflicting—requirements," *Id.*, including requirements arising under common law. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324

(2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

Frickenschmidt argues Plaintiffs' claims are expressly preempted by § 678 because they would impose requirements at odds with the USDA's regulations. Although the USDA does not define "gluten free," Frickenschmidt argues that the USDA necessarily relies on the FDA's definition of "gluten free" in the label approval process. To do so, Frickenschmidt cites statements from the FDA indicating that it "expect[s] to continue working with both FSIS and [Tobacco Tax and Trade Bureau] on matters relating to the use of the term 'gluten-free,' " 78 Fed. Reg. 47154-02, 47174 (Aug. 5, 2013), as well as blog posts from "Gluten Free Watchdog" and "Gluten Free Dietitian" stating that FSIS officials have instructed label applicants to follow the FDA's gluten free regulations. Critically for Frickenschmidt, these regulations allow products containing less than 20 ppm of gluten to be labeled gluten free. *See* 21 C.F.R. § 101.91(a)(d)(i)(A)(3). Because Plaintiffs' "allegations indicate that a product labeled gluten free must be completely devoid of gluten," Frickenschmidt reasons that their claims conflict with the USDA's requirements and are therefore preempted. (ECF 42 at p. 20.)

In their surreply, Plaintiffs respond that these blog posts and statements from the FDA are insufficient to impose a federal requirement entitled to preemptive effect. They insist that there is no conflict between their claims and federal

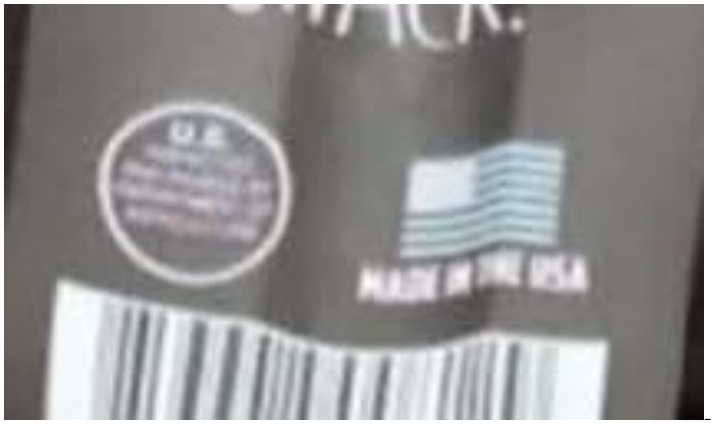
requirements because both the USDA and Frickenschmidt acknowledged that the Product was mislabeled in the recall announcement. Moreover, Plaintiffs argue that Frickenschmidt has failed to show any evidence that the Product's label was actually approved by the USDA.

While I agree that the statements cited by Frickenschmidt are insufficient to impose a federal requirement,[2] I disagree that the USDA imposes *no* requirements entitled to preemptive effect here. Even though the USDA does not define "gluten free," it nonetheless requires covered entities to submit labels for agency review before making that claim. This preapproval process imposes a federal requirement within the meaning of the FMIA's preemption clause. *See Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1288 (9th Cir. 2021) (FSIS review and approval imposes a federal requirement within the meaning of the Poultry Product Inspection Act's preemption clause). As the Supreme Court explained in *Riegel*: "[p]remarket approval . . . imposes 'requirements' under the [Medical Device Amendments of 1976] . . . . [I]t is in no sense an exemption from federal safety review—it is federal safety review." *Riegel*, 552 U.S. at 322-23 (2008). Thus, courts routinely conclude that the FSIS's preapproval of a label preempts state-law

[2] Courts have repeatedly rejected arguments that an agency's non-binding guidance imposes a federal requirement entitled to preemptive effect. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 RRM RLM, 2013 WL 4647512, at *10 (E.D.N.Y. Aug. 29, 2013); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340 (3d Cir. 2009); *Gabriele v. ConAgra Foods, Inc.*, No. 5:14-CV-05183, 2015 WL 3904386, at *5 (W.D. Ark. June 25, 2015).

claims that would effectively require the label to include different or additional markings. *See e.g.*, *Thornton v. Tyson Foods, Inc.*, 482 F. Supp. 3d 1147, 1157-58 (D.N.M. 2020), aff'd, 28 F.4th 1016 (10th Cir. 2022) (collecting cases).

I also disagree with Plaintiffs' argument that there is no evidence the FSIS actually reviewed and preapproved the Product's label. Plaintiffs note that Frickenschmidt does not "present a label showing FSIS approval nor present 'affidavits or other documentary evidence showing that the label was submitted to and approved by FSIS.' " (ECF 71 at p. 4 (quoting *Cohen*, 16 F.4th at 1289).) But a photo of the Product in the amended complaint shows an approval mark in the lower-left corner of the label:



Compare ECF 5 at p. 9 *with* 9 C.F.R. § 312.2(b)(1). *See also Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1203-04 (9th Cir. 2021) (finding that an inspection mark on product label demonstrated that the label was approved by the FSIS).

In any event, the fact that the Product was sold at all is sufficient evidence of preapproval. The Product could not have been sold unless the FSIS reviewed and

approved its label, including its gluten free claim, so the FSIS must have approved the Product's label. Other courts have similarly inferred label approval from the label's use in the marketplace. *See Thornton*, 482 F. Supp. 3d at 1156-57 ("FSIS necessarily approved the product labels. The FSIS approval process is required by federal law and the products could not be sold unless the seller complied with the process."); *Kuenzig v. Kraft Foods, Inc.*, No. 8:11-CV-838-T-24 TGW, 2011 WL 4031141, at *7 n.8 (M.D. Fla. Sept. 12, 2011) ("The regulations relating to the FMIA and PPIA are clear that Defendants' labels were required to be submitted to the FSIS for approval prior to their use, and given that the labels were, in fact used, the Court will presume that the labels received the FSIS's approval.").

In the sole case cited by Plaintiffs in which a court required a defendant to submit evidence of FSIS approval, the plaintiffs argued that the defendant improperly bypassed FSIS review. *Cohen*, 16 F.4th at 1289. The Ninth Circuit explained:

> In *Webb*, we found that label evidence alone was enough to conclude that a retained water claim was federal approved, but the plaintiff in that case did not challenge whether the label was reviewed by FSIS. By contrast, [Plaintiff] contends that [Defendant] used the generic approval process for its labels, improperly bypassing FSIS review. Here, we find that the mere existence of the label is insufficient to establish that it was reviewed and approved by FSIS. . . . Thus, *when the parties dispute whether FSIS review occurred at all*, the defendant must produce evidence that the label was approved by FSIS.

Id. (internal citations omitted) (emphasis added). Here, Plaintiffs do not contend that Defendants bypassed FSIS review. I will accordingly infer from the apparent USDA inspection mark on the label and the label's use in the marketplace that the FSIS reviewed and approved Defendants' label.

Because the FSIS reviewed the Product's label and necessarily determined that "gluten free" claim was not false or misleading, Plaintiffs' claims second-guessing that determination are preempted. The gravamen of each of Plaintiffs' claims is that they either paid too much for the Product because it was labeled gluten free, or that they would not have purchased the Product if they knew it was falsely labeled. Each of Plaintiffs' claims would therefore require the Product to have different markings than those approved by the FSIS and is accordingly preempted.

The USDA's recall announcement does not alter this conclusion. Rescissions of approval and product recalls are distinct processes governed by different regulations. *Compare* 9 C.F.R § 500.8 *with* 9 C.F.R. §§ 418.2-418.4. Thus, other courts have rejected the contention that a product recall vitiates premarket approval. *See In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1155 (D. Minn. 2009) (collecting cases); *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011) ("[P]roduct recalls do not create a presumption that FDA requirements have been violated.").

But even assuming that the recall announcement rescinded the FSIS's preapproval of the label, Plaintiffs claims would still be preempted. Liability for each of Plaintiffs' claims turns on whether the Product was false or misleading *at the time Plaintiffs purchased it*. Because the FSIS approved the gluten free label at that time, their claims second-guessing that approval are preempted, notwithstanding the USDA's later acknowledgment that the Product was mislabeled. *See Thornton*, 482 F. Supp. 3d at 1159 ("Even if the USDA made the wrong decision in determining that the labels were not misleading, it is unclear how that changes the preemption analysis."); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 134 n. 5 (Tex.App.2005) (disagreeing with assertion "that preemption, if applicable, evaporates if the FDA later determines that the [premarket approval] was wrongly granted" and explaining that defendant's "compliance with federal requirements setting the standard of care at the time the alleged tort was committed is [the] appropriate issue."); *In re Medtronic*, 592 F. Supp. 2d at 1156 (noting that the relevant issue is whether the product was approved at the time the alleged tort was committed).

I will therefore dismiss each of Plaintiffs' claims as preempted by the FMIA. I need not address Frickenschmidt's remaining arguments for dismissal.

Accordingly,

IT IS HEREBY ORDERED that Frickenschmidt's Motion to Dismiss First Amended Class Action Complaint and Strike Allegations or, In the Alternative, Motion for a More Definite Statement [41] is granted.

IT IS FURTHER ORDERED that Plaintiffs' amended complaint [5] is dismissed.

CATHERINE D. PERRY
UNITED STATES DISTRICT JUDGE

Dated this 27th day of March, 2023.